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| APPLICATION NO. | | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------|------|-------------|----------------------|---------------------|------------------|--|
| 08/410,539 | | 03/24/1995 | MATTHEW B. WHEELER | 7823/5 | 2654 | |
| 23644 | 7590 | 09/17/2003 | | | | |

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EXAMINER TON, THAIAN N

ART UNIT PAPER NUMBER 36 1632

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Application No. | Applicant(s) | | |
|-----------------|---------------------|--|--|
| 08/410,539 | WHEELER, MATTHEW B. | | |
| Examiner | Art Unit | | |
| Thai-An N. Ton | 1632 | | |

| Interview Summary | 00/4 10,559 | WHEELER, WATTHEW B. | |
|---|--|---|---------------------|
| interview Summary | Examiner | Art Unit 1632 I/A. If an agreement ction with regard reed would render the could render | |
| | Thai-An N. Ton | 1632 | |
| All participants (applicant, applicant's representative, PTO | personnel): | | |
| (1) <u>Thái-An N. Ton</u> . | (3) <u>Alice Martin</u> . | | |
| (2) <u>Deborah Crouch</u> . | (4) <i>Richard Lazarus</i> . | | |
| Date of Interview: 09 September 2003. | | | |
| Type: a)∑ Telephonic b)☐ Video Conference c)☐ Personal [copy given to: 1)☐ applicant 2 | 2) applicant's representative | ·} | |
| Exhibit shown or demonstration conducted: d) Yes If Yes, brief description: | e)⊠ No. | | |
| Claim(s) discussed: Of Record. | | | |
| Identification of prior art discussed: Of Record. | | | |
| Agreement with respect to the claims f) was reached. g |)⊠ was not reached. h)□ N | I/A. | |
| Substance of Interview including description of the general reached, or any other comments: <u>Discussed the pending redecision</u> . | | | |
| (A fuller description, if necessary, and a copy of the amend allowable, if available, must be attached. Also, where no callowable is available, a summary thereof must be attached. | opy of the amendments that w | | |
| THE FORMAL WRITTEN REPLY TO THE LAST OFFICE A INTERVIEW. (See MPEP Section 713.04). If a reply to the GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR FORM, WICHEVER IS LATER, TO FILE A STATEMENT OF Summary of Record of Interview requirements on reverse signal. | last Office action has already THE MAILING DATE OF THIS F THE SUBSTANCE OF THE | been filed, APP S INTERVIEW S | LICANT IS UMMARY |
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Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required



Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111. 1.135. (35 U.S.C. 132)

37 CFR §1 2 Business to be transacted in writing

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the guestion of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
 - (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

08/410,539 PRIDRITY:5/14/43 (68/063,095)

7823/5: U.S. Serial No. 08/410,539

Appendix: Claims on Appeal

- A method for making a chimeric ungulate comprising: 1.
- introducing an ungulate embryonic stem cell that has a first genetic (a) complement into a recipient embryo of the same species as the embryonic stem cell, said recipient having a second genetic complement, to form a chimeric ungulate embryo; and
- placing the chimeric ungulate embryo in an environment suitable for the (b) completion of development to form a chimeric ungulate.
- The method of claim 1, wherein the ungulate embryonic stem cell is pluripotent 2.
- The method of claim 2, wherein the ungulate embryonic stem cell is totipotent. 3.
- The method of claim 1, wherein the embryonic stem cell is introduced into the 4. embryo at a pre-implantation stage.
- The method of claim 4, wherein the pre-implantation stage is the blastocyst stage. 5.
- The method of claim 1, wherein the embryonic stem cell is derived from a first breed - 6. of ungulate and the recipient embryo is derived from a second breed of the same species as the first breed.
- The method of claim 1, wherein the first genetic complement is different from the - 9. second genetic complement.
 - The method of claim 9, wherein the first genetic complement comprises an exogenous 10. nucleotide sequence stably integrated into the genetic complement of the embryonic stem cell.

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- The method of claim 10, wherein the first genetic complement comprises a nucleotide sequence capable of being expressed to provide human Factor IX in recoverable form from the chimeric ungulate.
- The method of claim 10, wherein the first genetic complement comprises a nucleotide sequence encoding a protein selected from the group consisting of human blood proteins, human hormones, human growth factors, human cytokines, human enzymes, human hormone receptors, human binding proteins, antigens, translation factors, transcription factors, onco-proteins, protooncoproteins, human milk proteins, and human muscle proteins.
- 15. A method of isolating and purifying an embryonic stem cell culture, said method comprising:
- (a) preparing a first culture by culturing dissociated cells from an ungulate embryo in conditioned stem cell medium in the absence of a feeder layer; and
- (b) subculturing the first culture until a second stable culture with morphological features and growth parameters characteristic of an embryonic stem cell culture is established.
- The method of claim 15, wherein the dissociated cells from an ungulate embryo are obtained from an ungulate embryo which was developed *in vitro* in stem cell medium (SCM) on a feeder layer.
- 17. The method of claim 15, wherein the stem cell medium is conditioned by Buffalo Rat Liver Cells, and includes growth factors, vitamins, amino acids and antibiotics.

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- 18. The method of claim 17, wherein the stem cell conditioned medium (CSCM) comprises approximately 40% of stem cell medium (SCM) and approximately 60% of Buffalo Rat Liver Cell conditioned medium (BRL/CM)
- 19. The method of claim 15, wherein the morphological features of cells isolated from the culture comprise a round shape, as observed with the light microscope, a diameter of approximately 8-15 microns, and a cytoplasmic to nuclear diameter ratio of approximately 10-25:75-90, and wherein the growth parameters of the cells in culture comprise a doubling time of approximately 18-36 hours and multilayered rather than monolayered growth.
- 20. The method of claim 15, further defined as producing an embryonic stem cell culture which comprises at least 50% of cells that are capable of forming a teratoma or a teratocarcinoma when introduced into a host mouse.